In Re: Zetia (Ezetimibe) Antitrust Litigation

End-Payor Plaintiffs' Class Certification Hearing

July 7, 2020

Class Definition and Injury

Redacted Public Version

Class Definition Should Be Modified Based On The Evidence

- Motion for Class Certification moved beginning of class period to July 1, 2012, based on the evidence available then of when generic would have launched in but-for-world.
- Subsequent merits expert reports showed that generic would not have launched in but-for-world until November 2014 or later.
- Dr. Lamb has considered injury and damages for a range of but-for generic entry dates, should the jury find that a later date is appropriate.
- Analysis of rebates paid to OptumRx and certain Medicare Part D plans showed they were not injured, so further modification seeks to remove them from Brand-Generic Subclass.
- Modified Class Definition does not add new parties or claims.

Class Definition Should Be Modified Based On The Evidence

- Defendants' opposition primarily goes to the predominance of injury issues relevant to Rule 23(b)(3) class certification rather than the actual merits of the motion to modify
- This Court recognized that plaintiffs and the Court may modify a class definition in the DPP class certification decision – Report and Recommendation dated June 18, 2020 (ECF 967) at 6-8.

Proposed Class Definition

- All Third-Party Payor entities ("TPPs") within the Brand Subclass or the Generic Subclass defined herein that, for consumption by their members, employees, insureds, participants, or beneficiaries, and not for resale, indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Zetia or its AB-rated generic equivalents in any form, that was sold through a retail pharmacy, including mail-order pharmacies and long-term care pharmacies, in Alabama, Arizona, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia West Virginia and Wisconsin from November 15, 2014 (the "but-for generic entry date") through November 18, 2019.

Brand and Generic Subclasses

- Brand Subclass: TPPs that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of brand Zetia purchased between the but-for generic entry date and December 11, 2016, inclusive. Excluded from the Brand Subclass are Optum Health Part D Plans, Silverscript Part D Plans, Emblem Health Part D, Humana Part D Plans, Optum Health Managed Care Plans, and any TPPs that used one of these plans or OptumRx as its pharmacy benefits manager ("PBM") during this subclass period.

- Generic Subclass: TPPs that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of generic ezetimibe purchased between the generic entry date (December 12, 2016) and November 18, 2019, inclusive.

General Exclusions

The following entities are excluded from both subclasses:

a. Defendants and their subsidiaries and affiliates;

b. All federal and state governmental entities except for cities, towns, municipalities or counties with self-funded prescription drug plans;

c. All entities who purchased Zetia or generic Zetia for purposes of resale or directly from Defendants or their affiliates;

d. Fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members); and

e. Pharmacy benefit managers.

Exclusion Of Certain PBM Clients And Certain Medicare Part D Plans

- Certain entities are excluded because abnormally high rebates caused injury issues.
- This is not an individualized class member by class member inquiry about injury – it is a mechanical application of Merck's rebate data.
- As Dr. Lamb explained, entities receiving 20% or more rebates were excluded. Supplemental Declaration of Dr. Russell L. Lamb, Ph.D. dated May 15, 2020 ("Lamb Supp. Dec.") (ECF 945-1) at ¶ 4.

No Individualized Analysis Was Used To Exclude TPPs With Abnormally Large Rebates

- Apart from certain Medicare Part D plans, this exclusion does not name or analyze specific TPPs – it is based on the identity of the PBM.
- Mechanical analysis of common evidence: Merck's rebate data.
- Analysis does not go farther than amount of rebates – individual transactions and even individual TPPs are not analyzed.
- Defendants' comment about TPPs not being specifically named in the data after 2014 does not impact this analysis.
- Ms. Craft says the TPPs which are excluded can be identified.

The Proposed Class Definition Mirrors The One Certified in *Lidoderm*

- The *Lidoderm* court certified a similar EPP class definition with brand purchases only before generic entry, generic purchases only for most entities after generic entry, and an exception to include branded purchases by certain specifically named entities after generic entry – *In re Lidoderm Antitrust Litig.*, 2017 WL 679367, **3-4 (N.D. Cal. Feb. 21, 2017).

Distinction Between Injury And Damages

- Injury or impact is the fact of damage in any amount.
- Damages are the amount of injury.
- An entity may be injured even if it does not have recoverable damages. *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015).
- Damages may be established by a reasonable estimate. *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264-5 (1946).

Dr. Lamb Has Workable Methodologies To Show Injury With Common Evidence

Common Evidence Demonstrates That All or Nearly All Class Members Were Injured

- Actual experience in the market for Zetia and generic ezetimibe following generic entry demonstrates that earlier generic entry would have led to significantly lower prices.
- Defendants' documents confirm that generics quickly capture the majority of unit sales upon entry, resulting in significant cost savings that increases as the number of generics in the market increases.
- Academic literature shows that generics enter the market at lower prices than their brand-name counterparts and capture a significant share of the total unit sales for the drug.

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Direct Examination of Russell Lamb, Ph.D., May 1, 2020 ("Lamb Direct"), slide 3.

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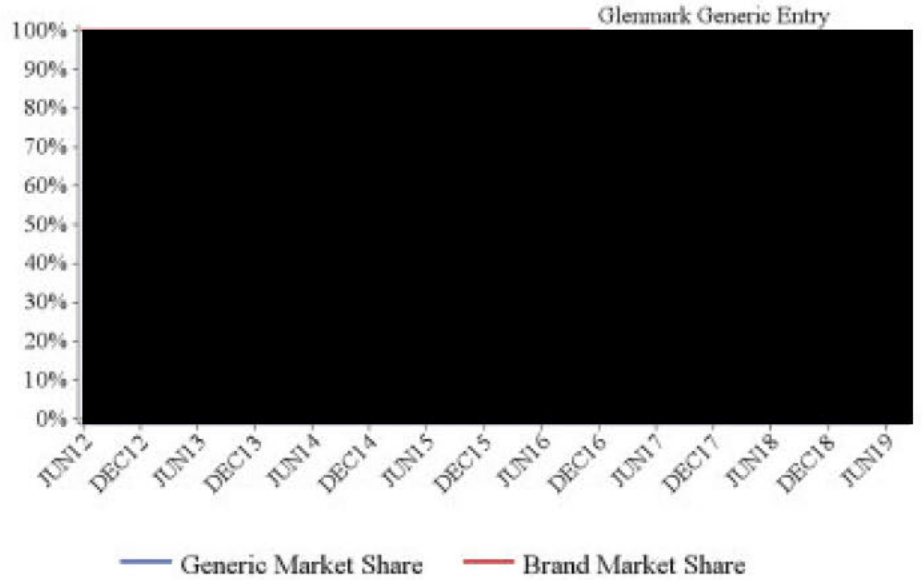
Dr. Lamb's Evidence of Common Impact

Brand Sales Quickly Converted to Less Expensive Generics

Figure 1
Brand and Generic Ezetimibe Market Shares



Source: IQVIA NPA Data.

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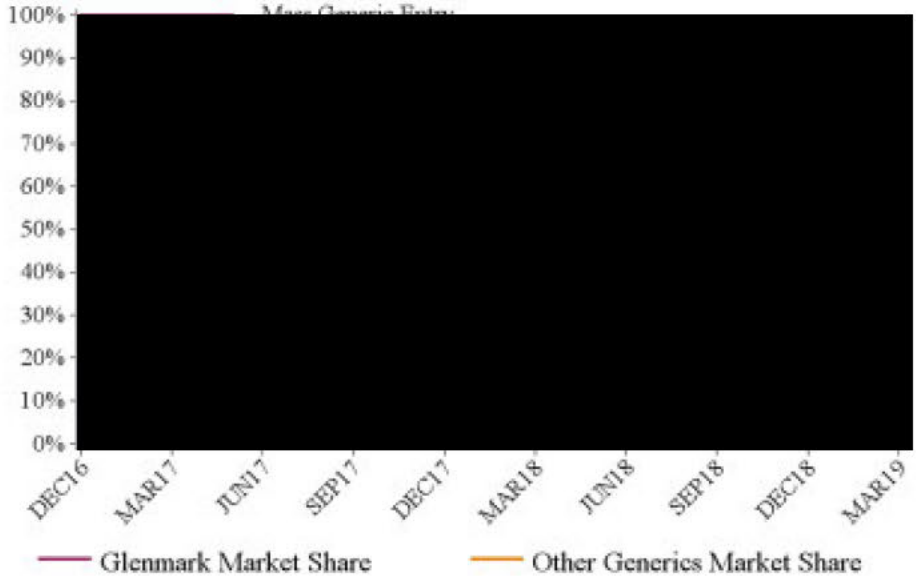
Dr. Lamb's Evidence of Common Impact

Generics Competed Against Each Other for Market Share

Figure 2
Generic Ezetimibe Market Shares



Source: IQVIA NPA Data.

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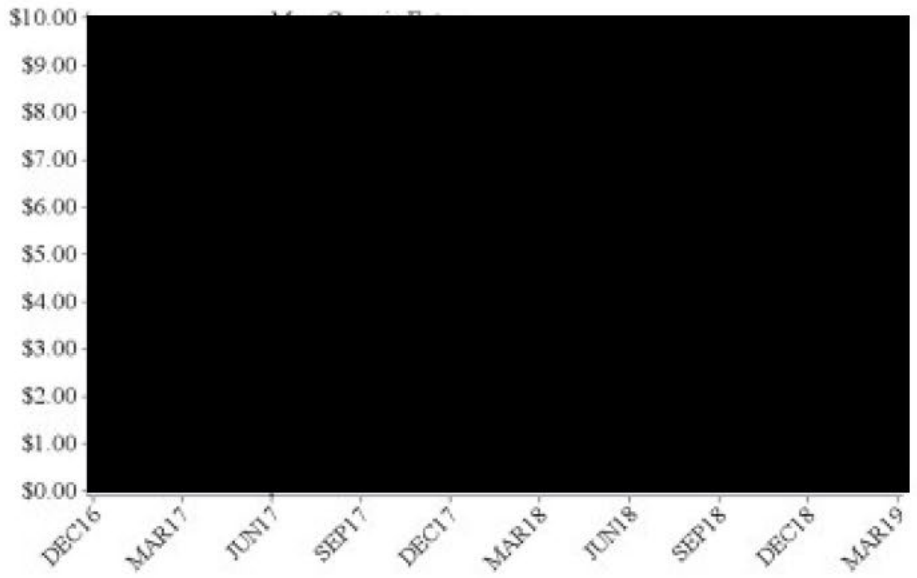
Dr. Lamb's Evidence of Common Impact

Competition Between Generics Drove Down Generic Prices

Figure 3
Average Generic Ezetimibe Prices



Source: IQVIA NPA Data.

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Dr. Lamb's Evidence of Common Impact

Merck Recognized That Generic Competition Would Drive Down Prices and Market Share

MRKZETIA000598792

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Dr. Lamb's Evidence of Common Impact

Merck Recognized That Generic Competition Would Drive Down Prices and Market Share

MRKZETIA_R000090753

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Dr. Lamb's Evidence of Common Impact

Merck Recognized That Generic Competition Would Drive Down Prices and Market Share

MRKZETIA_R000090757

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Dr. Lamb's Evidence of Common Impact

Academic Literature Establishes That Generics Enter at Lower Prices and Capture the Majority of Prescriptions

- Joseph Farrell, David Balan, Keith Brand, and Brett Wendling, "Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets," *Review of Industrial Organization*, Vol. 39, No. 4, October 1, 2011, 271-296.
- Murray L. Aitken, et al., "The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity," National Bureau of Economic Research, Working Paper No. 19487, October 2013.
- Henry Grabowski, Genia Long, and Richard Mortimer, "Recent Trends in Brand-Name and Generic Drug Competition," *Journal of Medical Economics*, Vol. 17, No. 3, March 2014, 207-214.
- Ernst Berndt, et al., "Authorized Generic Drugs, Price Competition, and Consumers' Welfare," Health Affairs, Vol. 26, No. 3, 2007.
- Federal Trade Commission, "Authorized Generics: An Interim Report," June 2009.
- Federal Trade Commission, "How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study," January 2010.
- Organisation for Economic Co-operation and Development, Directorate for Financial and Enterprise Affairs, Competition Committee, "Generic Pharmaceuticals," DAF/COMP/WD(2014)51, June 19, 2014

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Dr. Hughes' Analysis Is Unreliable

- Inappropriately compares actual brand prices to actual generic prices.
- Relies on cherry-picked examples.
- Focuses on the period immediately after generic entry.
- Incorrectly assumes that Tier 4 plans would have received large rebates.
- Wrongly claims that Medicare Part D plans would not have been injured.
- Ignores evidence that Merck would have launched an AG in the but-for world.

Dr. Hughes' Analysis Is Unreliable

- Dr. Hughes inappropriately compares actual brand prices to actual generic prices.
- Dr. Hughes' analysis compares actual brand prices to actual generic prices, which are the result of the anticompetitive conduct.
- The relevant analysis compares what Class members actually paid to what they would have paid absent the anticompetitive conduct, i.e., the but-for price.

Dr. Hughes' Analysis Is Unreliable

Dr. Hughes Inappropriately Compares Actual Brand Prices to Actual Generic Prices

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Dr. Hughes' Analysis Is Unreliable

A Relevant Analysis Compares Actual and *But-For* Prices

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Dr. Hughes' Analysis Is Unreliable

Dr. Hughes' Analysis Relies on Cherry-Picked Examples

Average generic cost is $[redacted] *less than brand*

Table 3

[redacted]

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Dr. Hughes' Analysis Relies on Cherry-Picked Examples

Exhibit 4 (Supplemental)

[redacted]

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Dr. Hughes' Analysis Relies on Cherry-Picked Examples

Average generic cost is $[redacted] *less than brand*

Table 4
Modified Hughes Exhibit 4 (Supplemental)
Showing all 30 Pill Claims for UFCW in January 2015

[redacted]

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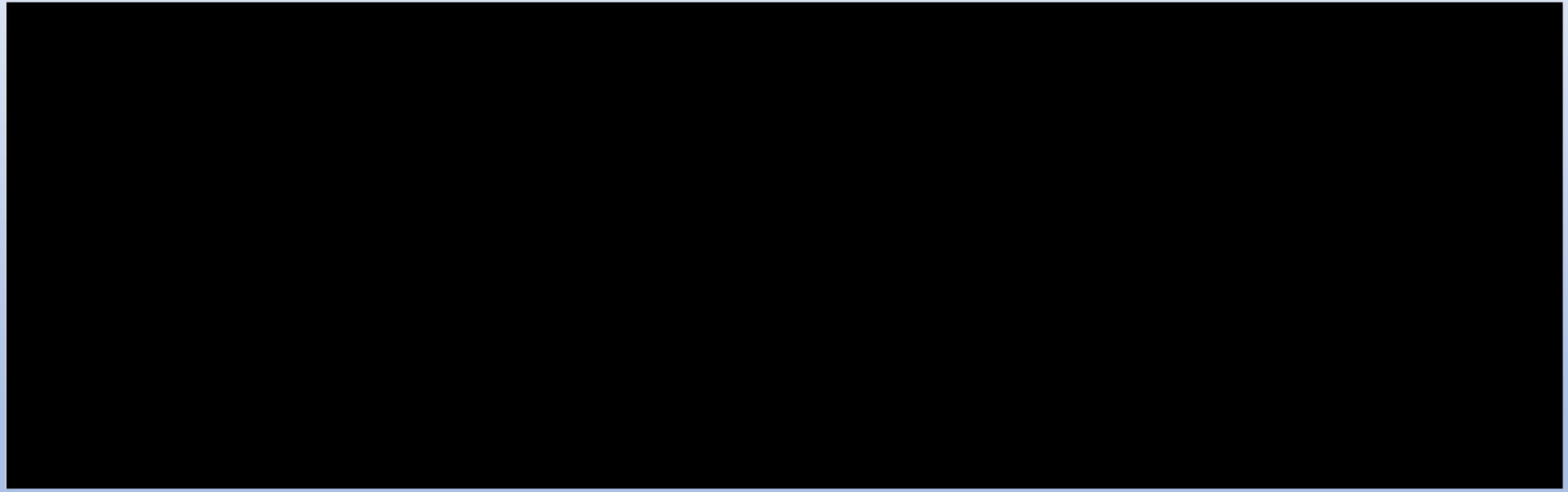
Dr. Hughes' Analysis Is Unreliable

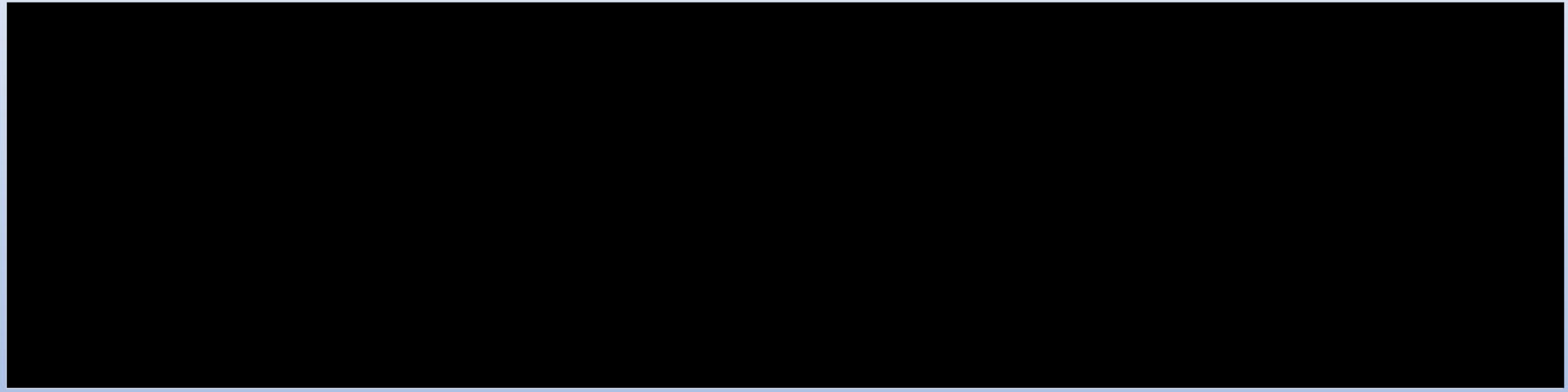
- **Dr. Hughes incorrectly assumes that Tier 4 plans would have received rebates.**
  - Most TPPs have drug formularies containing 3 or 4 tiers with higher tiers corresponding to higher cost sharing.
  - Dr. Hughes acknowledged [redacted]
  - Merck's documents show [redacted]

Dr. Hughes Incorrectly Assumes that Tier 4 Plans Would Have Received Rebates



MRKZETIA000967956

Dr. Hughes Incorrectly Assumes that Tier 4 Plans Would Have Received Rebates



MRKZETIA000523028

Tier 4 Plans Are Injured

Correcting Dr. Hughes' flawed assumption shows that plans that placed Zetia on Tier 4 or higher were injured

[1] Removes rebates and replaces brand WAC with the NPA brand price. Dr. Hughes's generic price floor is also removed.

[2] In addition to the corrections made in [1], copayments are recalculated using the average number of pills per prescription in the NPA data.

Table 2
Difference Between Actual Brand and But-for Generic Prices for Plans Placing Zetia on Tier 4 or Higher in Hughes Exhibit 9 (Supplemental)

Month	Hughes Brand-Generic Difference	Corrected Brand-Generic Difference [1]	Corrected Brand-Generic Difference [2]
11/1/2014	[redacted]	[redacted]	[redacted]
12/1/2014			
1/1/2015			
2/1/2015			
3/1/2015			
4/1/2015			
5/1/2015			
6/1/2015			
7/1/2015			
8/1/2015			
9/1/2015			
10/1/2015			
11/1/2015			
12/1/2015			
1/1/2016			
2/1/2016			
3/1/2016			
4/1/2016			
5/1/2016			
6/1/2016			
7/1/2016			
8/1/2016			
9/1/2016			
10/1/2016			
11/1/2016			
12/1/2016			
Percent of Class Period with injury	38%	81%	100%

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Dr. Hughes' Examples of Tier 4 Plans Were Wrong

- [redacted] EPPs' Supplemental Memorandum dated May 15, 2020 ("EPP Supp. Memo.") (ECF 945) at 5.
- [redacted] Lamb Supp. Dec. ¶19.
- Rebate paid to [redacted] *Id*. ¶20.

Dr. Hughes' Examples of Tier 4 Plans Were Wrong

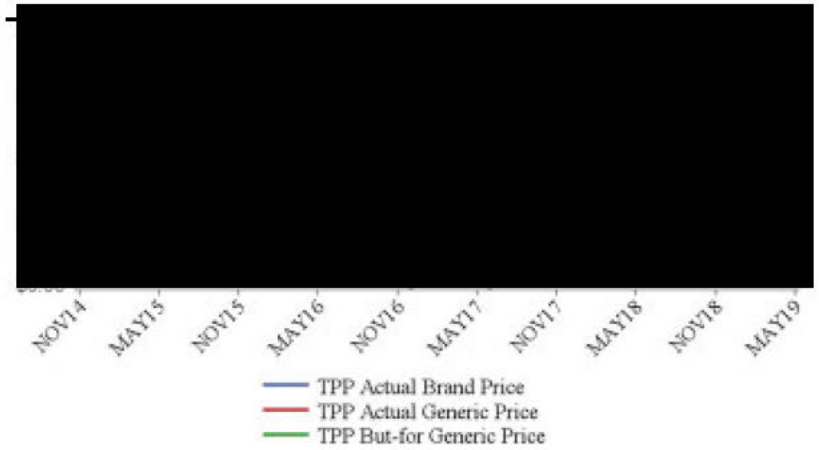
Hughes slide 12.

- [redacted] EPP Supp. Memo. at 6.
- [redacted] was not a Tier 4 plan. Lamb Supp. Dec. ¶19.
- The remaining plans received modest rebates: [redacted] Lamb Supp. Dec. ¶20.
- [redacted] are all Medicare Part D plans or Medicare Advantage plans. EPP Supp. Memo. at 6.

Dr. Lamb Shows Medicare Part D Plans Were Injured

Dr. Hughes Wrongly Claims That Medicare Part D Plans Would Not Have Been Injured

Figure 1.
Medicare Part D Actual and But-for Prices
Initial Coverage Phase



Sources: IQVIA NPA Data; Merck Rebate Data; Back-up to Hughes Class Report; MedPac.gov; Back-up to Hughes Supplemental Report; Kaiser Family Foundation; MRKZETIA000888792.
Note: Actual and but-for prices net of rebates, government reinsurance, and cost sharing.

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Dr. Lamb Shows Medicare Part D Plans Were Injured

Dr. Hughes Wrongly Claims That Medicare Part D Plans Would Not Have Been Injured

Medicare Part D plans were injured in every month during the initial coverage phase.

Table 1
Injury on Medicare Part D Plans in the Initial Coverage Phase
% of Months in Class Period with Injury

Medicare Part D Plan	Initial Period
[redacted]	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%
	100%

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Dr. Lamb Is Entitled To Rely On Single Injured Transaction Standard To Show Injury For Medicare Part D Plans

- "'Paying an overcharge caused by the alleged anticompetitive conduct on a single purchase suffices to show—as a legal and factual matter—impact or fact of damage.'" *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27, 28 n.23 (1st Cir. 2015) (citation omitted).

- "[A]ntitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset." *Id.*

Impact Is Immediately Established When A Purchaser Pays A Single Overcharge

- To prove injury a TPP must show that it incurred an overcharge on a single transaction. *Baker v. Carr*, 369 U.S. 186 (1962); *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 404 (D.R.I. 2019).
- Antitrust impact/injury occurs "the moment the purchaser incurs an overcharge, whether or not that injury is later offset" *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27, 28 n.23 (1st Cir. 2015).
- "[C]ourts will not go beyond the fact of this injury to determine whether the victim of the overcharge has partially recouped its loss . . . ." *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 254 n.14 (1972).
- Arguments that someone received a rebate or offset conflate impact/injury with damages – arguments that concern an offset relate to the *quantum* of the purchaser's damages, *not* the fact that it was injured. *See Brown v. Cameron-Brown Co.*, 92 F.R.D. 32, 45-46 (E.D. Va. 1981).
- Put differently, rebates may lessen the amount of damage a class member incurs but they *do not* erase or negate the initial damage as to each purchase. *See Loestrin,* 410 F. Supp. 3d 404-05; *Solodyn*, 2017 WL 4621777, at *17-18 (D. Mass. Oct. 16, 2017); *Nexium*, 777 F.3d 9, 28 n.23 (1st Cir. 2015); *Lidoderm*, 2017 WL 679367, 22-23, n.33 (N.D. Cal. Feb. 21, 2017); *Cardizem,* 200 F.R.D. 297, 317 (E.D. Mich. 2001).

Windham Does Not Support Defendants' Net Damages Injury Argument

- *Windham* involved thousands of tobacco auctions. *Windham v. American Brands, Inc.*, 565 F.2d 59, 66 (4th Cir. 1977).
- Plaintiffs' theories of liability varied between auctions. *Id.* at 67.
- Defendants cite a vague comment about propriety of off-sets, which appears to relate to the calculation of damages. *Id.* at 67.
- This Court, in discussing *Windham*, has held that defense arguments claiming benefits from challenged conduct might give rise to a right of set-off, but were not relevant to the issue of liability. *Brown v. Cameron-Brown Co.*, 92 F.R.D. 32, 45-46 (E.D. Va. 1981).

Defendants' Other Cases Do Not Support Their Net Damages Argument

- *Kerr v. Abbott*, 1997 WL 314419 (Minn. Dist. Ct. Feb. 19, 1997), considered rebates because plaintiffs' theory was that they should have benefited from rebates. *In re Restasis Antitrust Litig.* relied on *Nexium*'s injury standard and found that Minnesota did not require a different standard. 2020 WL 2555556, at **24, 31 (E.D.N.Y. May 5, 2020).
- *A&M Supply Co. v. Microsoft Corp.*, 654 N.W.2d 572 (Mich. Ct. App. 2002), is about whether plaintiffs could prove they incurred any overcharge and does not discuss net injury or set-offs. . *Restasis* relied on *Nexium*'s injury standard and found that Michigan did not require a different standard. 2020 WL 2555556, at **24, 31-32.
- *Kottaras v. Whole Foods Market*, 281 F.R.D. 16 (D.D.C. 2012), involved a literal shopping basket of items - claim was that a merger had inflated Whole Foods' prices generally, but most had actually gone down.
- *Exhaust Unlimited v. Cintas Corp*., 223 F.R.D. 506 (S.D. Ill. 2004) – users of a uniform and linen rental service challenged an ancillary environmental charge without proving whether it increased the cost of their rentals.
- *Kohen v. PIMCO*, 57 F.2d 672 (7th Cir. 2009) – commodities trading case where active traders in class could have benefited from artificial commodity prices.

Dr. Hughes' Erred In His Treatment Of Rebates In The Catastrophic Phase

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- Dr. Hughes claims that Dr. Lamb erred by attributing only 15% of rebates to plans.
- In fact, Dr. Hughes erred by attributing 100% of rebates to plans instead of 20%. Lamb Supp. Dec. ¶ 16.
- Defendants now admit the plans receive 20% of the rebates but do not acknowledge Dr. Hughes attributed 100% of the rebates to the plans. Def's Supp. Memo at 6.
- Dr. Lamb acknowledges that he should have used 20% but showed that the 5% difference was miniscule. Lamb Dep. of June 9, 2020, at 236:15-241:8.

Lamictal Is Inapposite

- Third Circuit faulted the district court for failing to engage in a rigorous analysis of whether plaintiffs could prove common injury. *In re Lamictal Direct Purchaser Antitrust Litigation,* 957 F.3d 184 (3d Cir. 2020).
- Focus of opinion was on the 180-day period when Teva had the sole generic on the market. *Id.* at 190.
- The brand manufacturer (GSK) had entered into a pay-for-delay deal with Teva which prohibited GSK from launching an authorized generic ("AG") to compete with Teva's generic during Teva's 180-day exclusivity period. *Id.* at 189.
- While GSK could not market an AG during the 180-day exclusivity period, it chose to compete with the generic by negotiating contracts with individual direct purchasers by lowering the price of branded Lamictal to generic levels, which allegedly caused Teva to set its generic price at an lower level than it planned during that period, a level which defendants there claimed to be no higher than if there were competition from an AG. Id. at 189.
- The district court incorrectly assumed injury at the moment the no-AG agreement prevented GSK from launching an AG: "This lack of analysis perhaps was due to the Court's assumption that antitrust injury here occurred 'at the moment the price of generic lamotrigine was artificially inflated by the no-AG agreement, even if GSK's Contracting Strategy later on possibly eroded some or all of the inflated price.'" *Id.* at 194.
- District court failed to analyze whether "the prices were never inflated to begin with because Teva preemptively lowered its prices before launching; thus some Direct Purchasers never suffered an overcharge." *Id.*
- The *Lamictal* district court compounded this error by treating the parties' arguments as disputes regarding the measurement of damages, rather than the existence of injury. *Id.*

Third Circuit Did *Not* Find Averages Improper Or Fault Dr. Lamb

- "While averages may be acceptable where they do not mask individualized injury, *see Gates v. Rohm & Haas Co*., 655 F.3d 255, 266 (3d Cir. 2011), we cannot determine whether that occurred here because of the lack of analysis. Accordingly, we vacate and remand for the District Court to analyze the evidence and arguments submitted as part of class certification." *Lamictal*, 957 F.3d at 194.
- At no point did the Third Circuit find that the analysis offered by Dr. Lamb was inadequate or unreliable or that the analysis of the defendants' economic expert was superior. *See id.* at 193-94.

No Assumption Of Injury Here

- Dr. Lamb did not assume injury from pay-for-delay deal with no authorized generic provision.
- Abundant evidence that Merck would have launched an authorized generic in but-for-world.
- Dr. Lamb has considered whether individual negotiations with PBMs and certain Medicare Part D Plans prevented injury.
- Proposed modified class definition removes potentially uninjured entities.